REMARKS

Claims 1-3, 5-13 and 33-45 are currently pending in the application. Claims 4 and 14-32 are canceled. Claims 1, 3, 5-13, 33, 35 and 42 are amended. Claims 43-45 are new.

The amendments and new claims find support in the specification and drawings as originally filed. For instance, myocardium and myocardial tissue is shown in Figs. 1a, 7a-e and 8, and is discussed at page 7, line 25 to page 8, line 7, page 8, lines 23-24, and page 14, line 22 *et seq.* The amendment to claim 33 is supported at page 10, lines 20-23, and support for amended claim 35 occurs at page 10, lines 15-23. Support for amended claim 42 can be found at page 11, lines 21-23. New claim 43 is supported by page 21, lines 3-10 and Figs. 6a and 6b. New claims 44 and 45 find support at page 10, lines 20-23 and page 21, lines 3-10, respectively. No new matter is added.

Telephonic Discussion

Applicant's representative appreciates the telephonic discussion conducted by Examiner Azpuru on November 29, 2006. Potential claim amendments were discussed, and Examiner Azpuru's suggestions have been incorporated into the claims as amended herein.

Support for the language of the various claims and amendments is also provided below.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

The majority of the rejections are under 35 U.S.C. § 112, on the grounds that the claimed subject matter is not supported by the specification. The Federal Circuit has held that there is no requirement of literal textual recitation of claimed subject matter, only that the application reasonably convey that the inventor had possession at that time of the later claimed subject matter. The Manual of Patent Examining Procedure also espouses this view ("The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." MPEP § 2163.02).

Claims 12 and 13:

Claims 12 and 13 were rejected because the specification does not describe "withdrawing the delivery system from its proximity to the muscle." As stated in the reply filed May 22, 2006, this subject matter is described at page 21, line 27 to age 22, line 3 (emphases added):

> "Thereafter, *withdrawal of the delivery system 18 then occurs in the standard manner, as shown in Fig. 7d*. One practice of this method requires repositioning the delivery system 18 within the left ventricular chamber 20 *after it is withdrawn* from the myocardium 10 so that another body 14 can be deposited within the myocardium 10. After the intended number of bodies 14 are positioned in the myocardium 10, *the delivery system 18 is withdrawn as shown in Fig. 7d*."

This step is also illustrated in FIG. 7d, which shows the withdrawal of the delivery system, with an arrow indicating the direction of movement.

Claims 1 and 11:

In the reply of May 22, 2006, support for the amendments and new claims was provided with reference to specific page and line numbers. All amendments and new claims were rejected as new matter. Specific support for the amendments and claims is provided below in the form of quotes, with specific passages emphasized.

Support for the amendment in claims 1 and 11 ("comprises external projections configured to create cavities between the tissue and the body sufficient to permit blood pooling in the cavities") can be found at page 11, lines 9-12:

> The *external face may have a projection that* imbeds itself into the muscle tissue and prevents normal muscle contraction or relaxation. The action of the projection upon the muscle tissue during a cycle of muscle contraction and relaxation *results in the creation of lacunae within the muscle that become filled with pooled blood*.

at page 18, lines 2-6:

> The *external projections* 28 of the body 14 may impede the motion of the implant, restraining it within the myocardium 10. Tearing or distortion of the filaments of the myocardium 10 result in the formation of intramyocardial cavities 30 surrounding the body 14. The space that is formed by these *intramyocardial cavities 30 can be partially filled by pooled blood 32 which can culminate in thrombus formation* 34.

and at page 18, lines 9-11 ("Thrombus formation 34 can occur in the absence of formation of intramyocardial cavities 30, with *blood pooling 32 taking place on the concavities 38 formed by the external surfaces 22 of the apparatus of the invention*.") and at page 20, lines 12-14 ("*The canted edges 82 of the inner tighter wound spring sections 72 provide a series of concavities 84 on the external surface 88 that can provide pockets for blood to collect*.").

Claim 33:

Claim 33 ("at least one opening in the body open to the lumen") is supported by the specification at page 10, lines 20-23:

> Alternatively, the drug releasing compound can be contained within *the lumen of a spring*, to be released between the spring coils as the heart contracts, or the compound can be formulated as a gel or resin that is *deployed between the coils of the spring*, to be released into the tissues with myocardial contraction.

page 11, lines 21-23:

> A bellows device is able to be compressed and to be expanded as it is acted upon by the myocardium. A bellows may enclose a cavity having drug-releasing compounds

> contained therein and optionally *the bellows may include a port for releasing the compound* from the cavity upon compression and expansion of the bellows spring.

page 12, lines 24-26 ("Alternatively, *the device may be tubular in shape with at least one sidewall removed, so that the internal cavity is in communication with the milieu external to the device*. In another embodiment, *the scaffold can include channels extending through the biocompatible body* to support tissue ingrowth."), page 20, lines 3-7:

> Fig. 3 depicts an alternative embodiment of an implantable body adapted for intramuscular implantation according to the systems and methods described herein configured as *a double helix spring 54 that encloses a lumen* 58. *This spring 54 has an inner helical structure 64 with an open pitch section* 60 and a tighter pitch section 62. Surrounding this inner helical structure 64 is an l outer helix 68 in an open pitch configuration.

page 20, lines 8-12:

> Fig. 4 depicts an alternative embodiment of an implantable body adapted for intramuscular implantation according to the systems and methods described herein configured as a flexible structure 70 comprised of a plurality of tighter pitch spring sections 72 connected by *two open pitch spring elements* 74. The flexible structure 70 is made of a continuous strand of flat rolled metal 78, *enclosing a lumen* 80.

page 20, lines 22-24 ("*The bellows 92 contains a central lumen* 100 into which can be dispersed various materials, including drug releasing compounds. *The mechanical motion of the bellows 92 would then result in the expulsion of the drug releasing compounds from its lumen 100.*") and page 21, lines 3-10 ("Fig. 6a depicts an alternative embodiment of an implantable body, and provides a longitudinally sectioned view of a cone-shaped body 112 made of rigid materials including a nondeformable housing 114 surrounding *a central tapered cavity* 118."), and Figs. 2-4, 5a, 5b, 6a and 6b.

Claim 34:

Claim 34 ("retained by a surface of the body") is supported at page 9, line 29 to page 10, line 5:

> In one embodiment, this apparatus has *at least one surface carrying a substance* capable of promoting localized angiogenesis. As one embodiment, this apparatus can include an implant formed of a biocompatible material that has *a drug releasing compound affixed to at least one of its surfaces*. *The surface carrying the substance capable of promoting localized angiogenesis can be coated with said substance or can be made of a material that comprises said substance*.

and at page 17, lines 25-28 ("The implantable body 14 can have *a coating of a drug containing or releasing compound* to provide for delivery of a therapeutic agent into the tissue, or to provide drugs that promote or aid angiogenesis or the implantable body can be entirely formed of such

drug releasing compounds."), and at page 19, lines 19-20 ("Additionally, *the devices described herein can be coated with or can carry drugs*.").

Claim 35:

Claim 35 ("the drug releasing compound is contained within a lumen of the body") is supported at page 10, lines 15-23:

> In yet another embodiment, *the device is designed to contain an internal reservoir into which can be placed a drug releasing compound* that is able to diffuse through the wall of the device. The reservoir can be constructed as an empty cavity within the device to be filled with a drug releasing compound. In this embodiment, the device is made of a material that is specifically permeable to the drug releasing compound within it, so that the contained drug can penetrate the device and contact the surrounding tissue. Alternatively, *the drug releasing compound can be contained within the lumen of a spring*, to be released between the spring coils as the heart contracts, or the compound can be formulated as a gel or resin that is deployed between the coils of the spring, to be released into the tissues with myocardial contraction.

at page 11, lines 21-23:

> A bellows device is able to be compressed and to be expanded as it is acted upon by the myocardium. *A bellows may enclose a cavity having drug-releasing compounds contained therein and optionally the bellows may include a port for releasing the compound from the cavity* upon compression and expansion of the bellows spring.

and at page 19, lines 19-20 ("Additionally, *the devices described herein* can be coated with or *can carry drugs*.").

Claim 37:

Claim 37 ("at least a portion of the body is formed from a drug releasing compound") is supported at page 9, lines 13-14 ("Such biochemical substances *can be imbedded in the structural material of the device*, or *can be carried on or affixed to its surfaces*."), and at page 9, line 29 to page 10, line 5:

> In one embodiment, this apparatus has *at least one surface carrying a substance* capable of promoting localized angiogenesis. As one embodiment, this apparatus can include an implant formed of a biocompatible material that has *a drug releasing compound affixed to at least one of its surfaces*. The surface carrying the substance capable of promoting localized angiogenesis *can be coated with said substance or can be made of a material that comprises said substance*.

at page 10, lines 13-14 ("In an alternate embodiment, *the implantable device is entirely made of a drug releasing compound*."), at page 17, lines 25-28 ("The implantable body 14 *can have a coating of a drug containing or releasing compound* to provide for delivery of a therapeutic

agent into the tissue, or to provide drugs that promote or aid angiogenesis *or the implantable body can be entirely formed of such drug releasing compounds*."), and at page 19, lines 19-20 ("Additionally, *the devices described herein can be coated with or can carry drugs*.").

Claim 38:

Claim 38 ("a radiation source carried by the body") finds support at page 10, lines 26-29 ("The radiation source *can be affixed to a surface of the implantable device*. Alternatively, the radiation source *can be carried within the implantable device*. In yet another embodiment, the radiation source *can be incorporated into the material employed to form the implantable device*.").

Claims 39:

Regarding claim 39 (a bellows device with "annular ripples"), applicants are making a *bona fide* attempt to respond to this rejection, but do not understand what is meant by "muscle relaxation is limited to myocardium." Claim 39 does not recite "myocardium." This claim is supported by Figs. 5A and 5b, and at page 20, line 24 to page 21, line 2:

> Fig. 5a illustrates an embodiment of a bellows 92 having an anterior solid metal obturator head 102 and a flexible metal cylinder 104 attached to it. The flexible metal cylinder 104 may be configured as a series of *annular ripples* 108 to permit flexion and extension of the device at specific locations along its length. The *annular ripples* 108 can pleat and unpleat in an accordion-like manner in response to axially directed stress. In continuity with the flexible metal cylinder 104 and the flexible *annular ripple* 108 is a terminal posterior cuff of deformable metal foil 110.

Claim 40:

Claim 40 ("external projections are defined by the tighter pitch spring sections") finds support in Fig. 4, and at page 20, lines 8-16:

> Fig. 4 depicts an alternative embodiment of an implantable body adapted for intramuscular implantation according to the systems and methods described herein configured as a flexible structure 70 comprised of *a plurality of tighter pitch spring sections 72 connected by two open pitch spring elements* 74. The flexible structure 70 is made of a continuous strand of flat rolled metal 78, enclosing a lumen 80. The *canted edges 82 of the inner tighter wound spring sections 72 provide a series of concavities 84 on the external surface 88 that can provide pockets for blood to collect*. Alternatively, there can be surfaces disposed on the internal face 90 of this flexible structure 70 that provide sites for blood to collect and coagulate.

Claim 42:

Claim 42 ("at least one opening") is supported at page 11, lines 21-23:

> A bellows device is able to be compressed and to be expanded as it is acted upon by the myocardium. A bellows may enclose a cavity having drug-releasing compounds contained therein and optionally *the bellows may include a port for releasing the compound* from the cavity upon compression and expansion of the bellows spring.

and also by Figs. 5a and 5b, and at page 20, lines 22-24 ("The bellows 92 contains a central lumen 100 into which can be dispersed various materials, including drug releasing compounds. The mechanical motion of the bellows 92 would then result in the *expulsion of the drug releasing compounds from its lumen* 100.").

Double Patenting:

Claims 1-13 and 33-42 were rejected on double patenting grounds in view of U.S. Pat. No. 6,692,520. The claims of that patent are directed to apparatus for promoting angiogenesis, while the current claims are directed to methods for promoting angiogenesis. Furthermore, the present application is a divisional application of U.S. Pat. No. 6,692,520. The present application is therefore shielded under 35 U.S.C. § 121 from a double patenting rejection based on the issued parent patent.

Applicant requests that all of the rejections be reconsidered and withdrawn, and that the application be passed to issue.

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